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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/301,842 04/29/99 FERNANDES

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QM32/0718

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| EXAMINER |
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| ART UNIT | PAPER NUMBER |

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DATE MAILED:

07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/301,842 | Applicant(s) FERNANDES ET AL | |
| | Examiner Ann Y. Lam | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Chin et al., 5,267,970. Chin discloses a baseplate (46) defining an opening therethrough, see Figure 1, said baseplate including a slit extending from said opening to an edge of said baseplate, see Figure 1; a fastener (37, 38 and 40) spanning said slit of said baseplate and operable to prevent enlargement of said slit; a tube-accommodating collar (31, 32 and 45) extending from an upper surface of said baseplate and disposed over said baseplate opening; a retainer (66) for axially retaining a medical tube within said collar, said tube extending through said baseplate opening; and a strap (103) for securing said baseplate to a patient.

As to claim 24, said collar (31, 32 and 45) has a height and includes a slit extending along substantially said entire height of said collar, see Figure 1, whereby a medical tube installed in the patient may be passed through said slits of said baseplate and collar to be received within said collar and extend through said baseplate opening.

As to claim 25, said collar includes a plurality of holes in communication with the interior of said collar, see Figure 1. The holes are at the distal and proximal end of the collar.

As to claim 26, said collar (31, 32 and 45) has a tube retaining portion (31 and 32) having a first diameter and a base portion (45) having a second diameter greater than said first diameter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-23, 28, 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al., 5,267,970, in view of Canale, 4,085,752, and further in view of Blair, 5,304,145.

Chin discloses the invention substantially as claimed, see above. However, Chin does not disclose an absorbent liner disposed on a lower surface of said baseplate for contacting the patient. However, Chin does not disclose an absorbent liner disposed on a lower surface of said baseplate for contacting the patient. Nor does Chin disclose an absorbent liner coextensive with said baseplate, or detachably mounted to said

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baseplate. Nor does Chin disclose the fastener to include a strap having first and second ends, each said end attachable to said baseplate on opposite sides of said slit.

Canale discloses a pad (10) having a liquid absorbent material to absorb fluid adjacent a colostomy appliance. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Canale absorbent pad for use with the Chin device in order to absorb fluids from the patient's body. As to claims 21 and 22, the Canale absorbent pad is substantially coextensive with said baseplate and is detachably mounted to said baseplate.

Moreover, Blair teaches that a belt (11) can be used to hold a tube in a patient, see column 3, lines 11-15. It would have been obvious to provide a belt as taught by Blair as a substitute for the adhesive in Chin in order to hold the Chin baseplate and Canale absorbent pad in place on a patient.

As to claim 23, Blair teaches that complementary Velcro fasteners (25 and 19) can be used to secure elements. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Velcro fasteners on the Canale absorbent pad and complementary Velcro fasteners on the Chin baseplate in order to secure the pad on the Chin baseplate, as would be desirable to keep the pad on the patient.

As to claim 28, Blair teaches that a belt member (11) may be formed to include a buckle (12) about the belt for its ease of disassembly and reassembly, see column 3, lines 11-15.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al., 5,267,970, in view Wortrich, 5,263,939.

Chin discloses the invention substantially as claimed, see above. However, Chin does not disclose said retainer including an arcuate body having first and second ends and adapted to fit around said collar, and a clamping element spanning said first and second ends of said arcuate body and operable to adjust the spacing between said first and second ends of said arcuate body to thereby control the amount of clamping force applied by said arcuate body to said collar.

Wortrich discloses a baseplate to be secured to a patient, said baseplate having an opening for receiving a cannula, and a clamp (30) to hold a cannula while allowing adjustment, angulation and rotation, see column 2, lines 36-39. The clamp (30) is equivalent to a retainer including an arcuate body having first and second ends and adapted to fit around said collar. Clamp (30) further comprises a clamping element spanning said first and second ends of said arcuate body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Wortrich clamp on the Chin device in order to hold a cannula while allowing adjustment, angulation and rotation, as taught by Wortrich.

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al., 5,267,970, in view of Esposito, 4,723,952.

Chin discloses the invention substantially as claimed, see above. However, Chin does not disclose the fastener as including a hook portion and a cooperating loop portion each attached to said baseplate on opposite sides of said slit.

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Esposito discloses an ostomy device having a belt wrapped around the torso of the user, the belt including Velcro, i.e., hook and cooperating loop portions, to secure the ostomy device on the user, see column 6, lines 62-64.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a belt that includes Velcro in order to maintain the Chin device on the user.

Response to Arguments

Applicant's arguments with respect to claims 19-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
July 16, 2001



ANHTUAN T. NGUYEN
PRIMARY EXAMINER

